Blood Bank
of San Bernardino
and Riverside Counties

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August 30, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket #98N-0581

To Whom It May Concern:

Of the three proposals in the above-numbered docket, only the third proposal, the codification of the requirements for infectious disease testing, may be without flaw. The first two proposals are both seriously flawed and require additional thought and, hopefully, extensive revision. Allow me to elaborate my concerns:

1. The autologous transfusion issue:

I have long been a very strong advocate for infectious disease testing of autologous blood. I have been such a strong advocate because I, like you, believe that we should do everything we can to protect the safety both of staff responsible for collecting and handling blood and patients who receive blood transfusions. Therefore, I have advocated testing of autologous blood so that infectious disease positive autologous units (HIV, HBsAg, HCV) can be identified and then discarded and such donors prevented from continuing to donate. The rationale behind this approach is well documented in your docket, in which you indicate that it is virtually impossible to prevent infectious disease positive units from inadvertently being transfused to the wrong recipient. It is very clear that labeling in any form has not interdicted inadvertent inappropriate transfusion. It is also unlikely that in the near future any modification will be developed that will be effective. Therefore, it makes absolutely no sense to me to begin to require that autologous units be tested only to aver in the same docket that such blood would be enabled to be shipped for transfusion and, in addition, that known infectious donors would be allowed to continue to donate and present risks both to the staff drawing them and the recipients potentially exposed to their units. I strongly support your mission, which is to protect the safety of the allogeneic blood supply. The very best way you can do that is by testing autologous units and discarding known infectious units before they are released for transfusion to hospitals throughout the United States which have already demonstrated that they cannot with certainty ensure that the unit will not go into an unsuspecting allogeneic recipient.

I realize that the decision enabling infectious disease positive units from autologous donors to be kept in the system, and in fact the whole issue of allowing known infectious autologous donors to donate blood for themselves, is an off-shoot of a misinterpretation of the Bragdon decision regarding equal treatment of "disabled" Americans, but I would hope now that this issue had made it to the level of a regulatory process that someone could re-evaluate it from a public health perspective. I personally do not feel that the Supreme Court would require that "disabled"Americans (i.e. individuals with AIDS or

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384 Orange Show Road, P.O. Box 5729, San Bernardino, CA 92412-5729 • Tel: 909-885-6503 • Fax: 909-381-2036

other infectious disease) have access to a therapeutic modality with minimal benefit if enabling them to have that procedure exposes healthy innocent people to undue risk. For example, should we allow individuals with active tuberculosis to fly on an airplane without a face mask because other healthy people are flying without face masks? Perhaps we should view it from the other perspective: When an allogeneic donor comes to the blood center and his or her blood tests positive for an infectious disease marker, we discard that unit; why don't we treat the autologous donor the same way?

2. The Supplemental Testing Issue:

I urge FDA strongly to reconsider making it a requirement to do supplemental testing on all blood that tests positive for an infectious disease marker on screening tests. My main concern has to do with first-time donors who test positive for HCV. In this situation, there is no need for look-back or product retrieval, and there is very little incentive to consider any re-entry mechanism. In addition, the supplemental test for HCV is quite expensive. Does the FDA really have the authority to require blood centers to perform expensive supplemental testing when there is absolutely no impact whatsoever on blood safety, purity or potency?

I believe that blood centers have an obligation to counsel donors when they have a positive test for an infectious disease marker and I believe those donors need to be advised to seek follow-up testing when appropriate and certainly to seek medical care and input. Other than for HIV and HBsAg, for which we gladly do supplemental testing so that we can inform donors as quickly and as completely as possible about the need to seek medical care, I don't believe we are the appropriate agency, nor do we have the resources, to provide expensive medical diagnostic testing for blood donors. However, if the FDA would be willing to provide expense reimbursement for this public health service, I believe that it would be possible for us to arrange such testing. Absent such reimbursement, it is inappropriate to require supplemental testing when there would be no discernable impact on transfusion safety.

Thank you very much for the opportunity to comment on the proposed regulations. I hope the FDA will view with great seriousness the comments above as well as the numerous other comments they will undoubtedly receive in order to reach the best decision for all patients requiring a blood transfusion and all staff involved in the collection and provision of that service.

Sincerely yours,

Arthur J. Silvergleid, M.D.
Medical Director and CEO

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